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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,002	05/20/2005	Ugur Sahin	4883-0001	7473
27123	7590	09/21/2007		
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER REDDIG, PETER J	
			ART UNIT 1642	PAPER NUMBER
			NOTIFICATION DATE 09/21/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com  
Shopkins@Morganfinnegan.com  
Tquinones@Morganfinnegan.com

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 10/537,002	Applicant(s) SAHIN ET AL.	
	Examiner Peter J. Reddig	Art Unit 1642	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 27 August 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

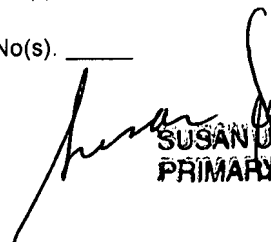
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
**SUSAN UNGAR, PH.D.**  
**PRIMARY EXAMINER**

Continuation of 3. NOTE: The newly added claims and limitations are drawn to issues that require new considerations and search.

Continuation of 11. does NOT place the application in condition for allowance because: Claims 99-104 remain rejected under 35 USC112, first paragraph, for the reasons previously set forth in the Office Action of June 27, 2007, section 5, pages 3-4.

Applicants argue that claims 99-101 have been amended to disclose a methodology of diagnosing stomach, lung, and pancreatic cancers. Applicants argue that the Examiner's rejection has been rendered moot. The Examiner states that the instant specification enables the diagnosis of stomach and lung cancers. (See page 4 of the Office Action dated June 27, 2007). The applicants respectfully argue that the diagnosis of pancreatic cancer is also enabled in the instant specification. (See Example 4, pages 67-70 of the translated priority document (German Application No. 102 54 601.0); and Example 4, pages 92-99 of the instant specification.) Additionally, the applicants respectfully argue that the diagnosis of esophageal cancer is also enabled in the instant specification. (See Table 3A of the instant application, page 94.) Independent claim 99 has been amended to recite a method of diagnosing stomach, lung, and pancreatic cancers. Independent claim 117 recites a method of diagnosing esophageal cancer. Applicants respectfully argue that the instant specification, specifically Example 4, provides a complete description so that a skilled artisan can make and use the claimed invention.

Applicants' arguments have been carefully considered, but have not been found persuasive because the amendment has not been entered and will not be entered for the reasons set forth above, therefore the claims have not been amended and the rejections remain for the reasons previously set forth.

Claims 99-104 remain rejected under 35 USC112, first paragraph, for lacking an adequate written description for the reasons previously set forth in the Office Action of June 27, 2007, section 6, pages 4-5.

Applicants argue that they have amended the claims for clarity. Specifically applicants have amended independent claim 99 which is now directed to detecting the expression of a tumor-associated antigen in a biological sample, where the tumor-associated antigen is either the polypeptide of SEQ ID NO:16 or a polypeptide encoded by a nucleic acid of SEQ ID NO:7.

Applicants' arguments have been carefully considered, but have not been found persuasive because the amendment has not been entered and will not be entered for the reasons set forth above, therefore the claims have not been amended and the rejections remain for the reasons previously set forth.

The priority data of the instant application remains May 20, 2005, for the reasons previously set forth in section 4, pages 2-3 of the Office Action of June 27, 2007.

Applicants argue that the priority application, German Application No. 102 54 601.0, sets forth that SEQ ID NO:16 encodes the claudin-18A2.1 translation product that "can be used as a marker to detect tumors of the upper gastrointestinal tract, in particular stomach carcinoma and pancreatic carcinoma." (See Example 4, page 67, lines 15-20.) There is sufficient support within this application to show a correlation of mRNA levels and the protein that is translated by said mRNA. (See Example 1, pages 59-62 and Example 4, pages 67-70.)

Applicants' arguments have been carefully considered, but have not been found persuasive because the amendment has not been entered and will not be entered for the reasons set forth above, therefore the claims have not been amended and thus for the reasons previously set forth, the disclosure of the prior-filed application, German Application No. 102 54 601.0, fails to provide adequate support or enablement because 102 54 601.0 only teaches detecting claudin 18A2.1 mRNA in tumors (see Example 4, p. 67-70, Table 3 and Fig. 5) and for the reasons set forth on pages 12-14 of the Office Action of October 17, 2006, the detection of mRNA does not predictably extrapolate to the detection of proteins. Additionally Example 1, pages 59-62, does not provide support for the instant claims as it is not drawn to claudin 18A2.1/SEQ ID NO: 16.

Applicants argue that PCT article 11 states that the PCT application must be filed "in the prescribed language." German is one of the accepted languages of the PCT receiving offices, particularly the European patent office where this application was submitted. Thus, this application was submitted in an acceptable language and should receive the priority date of German Application No. 102 54 601.0. Furthermore, applicants respectfully point out that an English language translation of the U.S. national phase entry application was filed concurrently with the German PCT application in the U.S. receiving office on May 20, 2005. In view of the above facts, applicants respectfully request that the instant specification claims the benefit of both the PCT and German priority dates, November 21, 2003 and November 22, 2002, respectively.

Applicants' arguments have been carefully considered, but have not been found persuasive because the international application is required to be in the English language to be accorded the international filing date, see 37 CFR 1.431 (b)(2), 35 U.S.C. 361(c), and PCT Art. 11(1)(ii).